

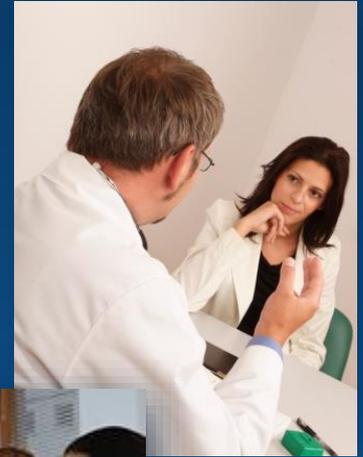
# Biocom CRO Presents: Concept to Commercial: A Clinical and Regulatory Outlook

October 11, 2017



# Therapeutics Inc.

*The Dermatology CRO*



**Hello Mr. CEO – Here is what I think you need to know**

# Agenda

- TI overview
- B – school 101
- Planning
- Gap Management
- Transition Point Navigation
- Serving your Constituency



# Therapeutics, Inc. - *The Dermatology CRO*

- A Fully Integrated CRO from Concept → FDA Approval
  - Turn-Key Product Development: Program Management, Formulation, CMC, Non-Clinical, Clinical, Regulatory Affairs
  - All Categories: Drugs, Devices, Biologics
  - All Dosage Forms: Topical, Oral, Injectable
  - Dermatology Focus (~85%) / Other (~15%)
- Development Focus
  - Not Discovery; Not Sales & Marketing
- Recent Five Years
  - Filed > 15 IND/IDEs
  - Conducted >90 studies in >10,000 subjects
  - Multiple product approvals
- Headcount: ~75
- Founded: 1997

# B School 101

- Business
  - Selling the concept ; raising capital
  - TEAM just as important as the technology – Diversity is key
  - Selective use of KOL's at early stage
  - Be clear on business case objectives – but not rigid
  - Focus on the short-term priorities and milestones (Critical path)
  - Set the culture norms early and re-inforce frequently
  - Don't forget to pause and reflect

# Planning – Many paths to failure, few to success

- Have specialized planning / tracking / PM staff
- Use tools (ie MS Project) as direction – setting, milestone tracking, and communication
- Manageable plans ; beware of thousand-line MS schedules
- Contingencies – development of ‘what – if’ scenarios
- Update plan as frequently as needed
- My two rules
  - Take no small slips
  - Underspent = behind schedule (most of the time)
- Define processes for transitions

# Mind the Gap(s)

- 'Jack of all trades' expertise is essential
- Formal transition (stage-gate) reviews
  - What is missing? What is superfluous?
  - Call options for next stage and beyond
- Seek out alternate points of view
- Treat all functional disciplines with equal care and concern
  - It really does take a team

# Transition Point Essentials

- Express the last phase data, and full program data in easy-to-interpret form
- Define clearly your next phase objectives
  - Early Kill strategy vs one pony scenario
  - If moving ahead, what is needed, when, and who is to deliver?
- View your program data objectively. Define best, likely, and worst case risk scenarios.
- Evaluate the data. Get consensus. Take measured risks where appropriate.
- Remember products are like children. They have their own personality. Continually revise your expectations and objectives in light of this fact.

# Serving Multiple Masters

- Investors, Regulators, Commercialization partners, etc all view your data and project differently (in most cases)
- Balancing is an art form, not a science.
- Its OK to be uncertain. That's the nature of this business.
- Failure is a reality. But it does not have to be fatal.
- Shoot for early small successes to build momentum. More games are won on base hits than grand slams.
- Be clear, proactive, and collaborative with FDA.
- Clinical studies answer **one** question well if properly designed and executed.

Questions?

Thank You for your time this morning

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